UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,758	05/15/1998	DENNIS R MORRISON	MSC-22939-1-	8692

24957 7590 06/14/2007

NASA JOHNSON SPACE CENTER
MAIL CODE AL
2101 NASA PARKWAY
HOUSTON, TX 77058

EXAMINER	
SOROUSH, LAYLA	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/079,758	MORRISON ET AL.	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,30-35,37,39,40,73,74,77,85,93,94,97,98 and 114-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,30-35,37,39,40,73,74,77,85,93,94,97,98 and 114-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the Applicant's reply filed April 2, 2007 to the Office action mailed on January 17, 2007.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1, 6,30-35, 37, 39-40, 73-74, 77, 85, 93-98, 113 over McGinty (US Pat No. US 5288502A, previously presented) in view of Gardner (US 4532123 A), Busnel et al. (US 4930522 A), Scher et al. (US 5846554 A) and Roth et al. (Rofo. 1979 Sep;131(3):317-21 Abstract provided) McGinty (US Pat No. US 5288502A, previously presented) in view of Gardner (US 4532123 A), Busnel et al. (US 4930522 A), Scher et al. (US 5846554 A) and Roth et al. (Rofo. 1979 Sep;131(3):317-21 Abstract provided) is persuasive. Therefore, the rejection is herewith withdrawn.

See new rejections below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 30-35, 37, 39, 40,73-74, 77, 93-94, 114-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiroshi et al. (JP 06-256728 A) in view of Sang et al. (US Pat No. 5039559) and Sugarbaker et al. (Improved detection of focal

lesions with computerized tomographic examination of the liver using ethiodized oil emulsion (EOE-13) liver contrast).

Hiroshi et al. teaches a breakable microcapsule comprising a ferromagnetic. Generally, the alloy which makes a principal component simple substances, such as iron, nickel, chromium, copper, aluminum, titanium, zinc, and tin, and it thru/or a constituent, the stainless steel like SUS340, the alloy like a permalloy, the metallic oxide like a ferrite, Fe-nickel-P, the amorphous alloy like Fe-Co, etc. are used. A ferromagnetic can be used with proper gestalten, such as powder, and a staple fiber, a plating object to plastics fine particles.

About the microcapsule which a material is made to contain, it is arbitrary, and is suitably chosen according to the purpose of using a material. The particle size of a microcapsule is 100 micrometers or less, above all, although the particle size of a microcapsule is desirably about 1-30-micrometer. The wallplate (capsule) is made of, i.e., polyvinyl alcohol, a polyvinyl butyral, polymethylmethacrylate, a polyacrylonitrile, a polyvinylidene chloride, and polysulfone which is of heating melting nature matter, and may be destroyed by thermal expansion.

The reference fails to teach a plurality of internal immiscible liquid phases and a coencapsulate surrounding the magnetic particles.

Sang et al. teaches ceramic particles of below 100 microns in diameter containing an inert liquid immiscible phase: dispersion of magnetic material such as iron

wherein "the magnetic material or the low Curie point magnetic material encapsulated in an inorganic oxide...the particles having the property of being readily brought down out of dispersion by application on a magnetic field and of being readily re-dispersed after removal of the magnetic field (col 2 lines 63-70)." The magnetically attractable particles may be coupled to a biologically or organic molecule with affinity for or the ability to adsorb certain other biological or organic material.

Sugarbaker et al. teaches improved detection of focal lesions with computerized tomographic examination of the liver using ethiodized oil emulsion (EOE-13) (iodinated poppy seed oil—comprise hydrocarbons) liver contrast.

It would have been obvious to one of ordinary skill in the art to incorporate a plurality internal immiscible liquid phases and coat the magnetic particles. The motivation to make such an incorporation is because Sang et al. teaches that multiple emulsions such as water in oil in water emulsion are more stable (meeting limitation of claims 93 and 94) (col 5 lines 30-60) and coating the magnetic particles are used to avoid contamination of the biological media with the inner potentially toxic core. The motivation to incorporate an internal immiscible liquid such as ethiodized oil is because Sugarbaker et al. teaches improved detection of focal lesions with computerized tomographic examination of the liver using said emulsions. Therefore, a skilled artisan would have had reasonable expectation of successfully producing a more stable and safe composition with improved detection of focal lesions with computerized tomographic examinations.

Claims 85,97, 98, and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiroshi et al. (JP 06-256728 A) in view of Sang et al. (US Pat No. 5039559), as applied to claims 1, 6, 30-35, 37, 39, 40,73-74, 77, 93-94, 114-115 above and further in view of Borrmann et al. (DE 19606804 A1).

Hiroshi et al. fails to teach an anti cancer drug incorporated in the microcapsule as clained.

Borrmann et al. teaches a method for the scheduled release of an active substance, which is contained in a preferably microscopically small container where the container releases, according to a schedule, the active substance which was previously transported in the container, particularly for medical therapy, advantageously for targeted medication, characterized in that the container, after a transport of the active substance, is opened after a predetermined scheduled local release area has been reached for the targeted release of the active substance. The method is characterized in that the action substance consists of particles movements and/or structure formation of which can be influenced by a magnetic field, and in that the action substance-containing container is exposed according to a schedule to a locally limited magnetic field.

It would have been obvouis to one of ordinary skill in the art at the time of the invention to incorporate a drug into the microcapsule of Hiroshi et al. The motivation to make such an incorporation is because there is scheduled release of an active substance which is advantageous for targeted medication. Hence a skilled artisan would have had reasonable expectation of successfully producing a scheduled release targeted medicament.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44, 83, and 84 of U.S. Patent No. 5827531. The invention herein is drawn to a microcapsule comprised of a plurality of internal, immiscible liquid phases;a flexible polymer outer membrane encapsulating the liquid phases, the polymer outer membrane having a melting temperature; and one or more energy absorbing trigger particles contained in an internal liquid phase in contact with the polymer outer membrane, wherein the one or more energy absorbing trigger particles are co-encapsulated with the plurality of internal, immiscible liquid phases by the flexible polymer outer membrane, wherein the one or more energy absorbing trigger particles sediment in the internal liquid phase in contact with the polymer outer

membrane, wherein at least one of the one or more energy absorbing trigger particles are in contact with the polymer outer membrane, wherein the one or more energy absorbing trigger particles have a higher specific absorption rate for magnetic, radiofrequency, microwave, or ultrasound energy than the specific absorption rate of the polymer outer membrane, and wherein the temperature of the one or more energy absorbing trigger particles is increased by absorbing the energy to melt at least a portion of the polymer outer membrane whereas, the U.S. Patent is a multi-layered microcapsule, comprising:

a first layer comprising a first solvent, a first microcapsule layer-forming compound soluble in said first layer and immiscible with a second layer, a co-solvent, oil, and water; said second layer immiscible with said first layer, said second layer comprising a second solvent, a second microcapsule layer-forming compound soluble in said second layer and immiscible with said first layer, a surface active agent, and a salt; said surface active agent having a hydrophilic/lipophilic balance value greater than that of said first microcapsule layer-forming compound; and, said second microcapsule layer-forming compound having a hydrophilic/lipophilic balance value lower than that of said surface active agent.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a similar microcapsule used for the same purposes.

Claims 1 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,7,8, 11, 14, 38, and 43 of U.S.

Patent No. 6099864. The invention herein is drawn to a microcapsule comprised of a plurality of internal, immiscible liquid phases;a flexible polymer outer membrane encapsulating the liquid phases, the polymer outer membrane having a melting temperature; and one or more energy absorbing trigger particles contained in an internal liquid phase in contact with the polymer outer membrane, wherein the one or more energy absorbing trigger particles are co-encapsulated with the plurality of internal, immiscible liquid phases by the flexible polymer outer membrane, wherein the one or more energy absorbing trigger particles sediment in the internal liquid phase in contact with the polymer outer membrane, wherein at least one of the one or more energy absorbing trigger particles are in contact with the polymer outer membrane, wherein the one or more energy absorbing trigger particles have a higher specific absorption rate for magnetic, radiofrequency, microwave, or ultrasound energy than the specific absorption rate of the polymer outer membrane, and wherein the temperature of the one or more energy absorbing trigger particles is increased by absorbing the energy to melt at least a portion of the polymer outer membrane whereas, the U.S. Patent is a method of in situ activation of a drug comprising: providing a microcapsule wherein the microcapsule comprises two or more internal liquids, wherein each internal liquid is immiscible with the other internal liquids, and all of the internal liquids are enclosed together in a single polymer shell, a drug precursor associated with at least one internal liquid phase; and exposing the microcapsule to an energy source in an amount effective to promote physical mixing of the immiscible liquid phases and to increase the activation kinetics of activation of the drug precursor.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a similar microcapsule used for the same purposes.

Response to Arguments

Applicant's arguments filed on April 2, 2007 have been considered.

The arguments made against the art rejections of claims 1, 6,30-35, 37, 39-40, 73-74, 77, 85, 93-98, 113 are considered moot in view of new rejections.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER